IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

MICHAEL BAZZREA, *et al.*,

Plaintiffs,

v.

ALEJANDRO MAYORKAS, *et al.*,

Defendants.

Case No. 3:22-cv-00265

DEFENDANTS' OPPOSITION TO
PLAINTIFFS' MOTION FOR AN EVIDENTIARY HEARING

INTRODUCTION

Despite the fact that this case has not even proceeded past the pleading stage, Plaintiffs have filed a freestanding "motion" that asks the Court to convene an evidentiary hearing and to permit discovery so that it can make two determinations:

(1) Whether specific vaccine lots within the Department of Defense's ("DoD") possession are, in fact, lots of Comirnaty—the BLA-approved COVID-19 vaccine produced by Pfizer, Inc. and BioNTech—which Plaintiffs contend will resolve whether their claims under 10 U.S.C. § 1107a and 21 U.S.C. § 360bbb-3 are moot; and

(2) Whether the United States Coast Guard violated Plaintiffs' and putative class members' rights under the Religious Freedom Restoration Act ("RFRA"), the First Amendment's Free Exercise Clause, and the Fifth Amendment's Procedural Due Process Clause by allegedly using "digital tools" to deny service members' requests for religious accommodations from the Coast Guard's COVID-19 vaccination requirement without any consideration of their individual circumstances.

See Pls.' Mot. for Evidentiary Hearing ("Mot.") at 1, 21–22, ECF No. 50. As set forth below, this request should be rejected for several reasons. As an initial matter, Plaintiffs are asking the Court to engage in freewheeling factual inquiries for the purpose of deciding a jurisdictional

question and the ultimate merits of three of Plaintiffs' claims. But such a request to proceed straight to trial, even before Defendants have responded to the Complaint, is clearly outside the ordinary course of litigation. Even setting that consideration aside, Plaintiffs offer no credible basis on which the Court should hold an evidentiary hearing at any stage on any issue. Notably, the factual inquiry that Plaintiffs urge this Court to undertake regarding the "legal status" of specific lots of Comirnaty is wholly immaterial to the disposition of their claims and, if the merits of those claims are reached, should in any event be resolved based on the Food and Drug Administration's ("FDA") official records and its officer's sworn testimony—evidence that Plaintiffs have failed to rebut. Plaintiffs also offer no credible basis on which to hold an evidentiary hearing into the Coast Guard's handling of religious exemption requests. For those reasons, set forth further below, the Court should deny Plaintiffs' motion.

BACKGROUND

Several months ago, five Coast Guard members filed this lawsuit to challenge DoD's and the Coast Guard's COVID-19 vaccination requirements. *See* Class Action Compl. for Decl. & Inj. Relief ("Compl."), ECF No. 1. Plaintiffs allege that these vaccination requirements violate, *inter alia*, the Religious Freedom Restoration Act ("RFRA"), the First Amendment's Free Exercise Clause, the Fifth Amendment's Due Process Clause, and two statutory provisions, *see id.* ¶¶ 122–83, that impose notice requirements for products authorized only for "emergency use," *see* 10 U.S.C. § 1107a(a); 21 U.S.C. § 360bbb-3.

In August 2022, Plaintiffs filed a motion for a preliminary injunction, seeking to enjoin DoD, the Department of Homeland Security ("DHS"), and the Coast Guard from enforcing the military's COVID-19 vaccination requirements against Plaintiffs. *See* Pls.' Mot. for Prelim.

Inj. ("PI Mot."), ECF No. 17. Defendants opposed the motion because Plaintiffs had failed to satisfy any of the factors necessary to obtain a preliminary injunction. *See* Defs.' Opp. to Pls.' Mot. for Prelim. Inj. ("PI Opp."), ECF No. 22. Regarding Plaintiffs' § 1107a and § 360bbb-3 claims, Defendants argued that these claims were unlikely to overcome several threshold issues, including standing and mootness, and would also fail on the merits. *Id.* at 11–12. As Defendants explained, each unvaccinated Plaintiff can comply with the military's COVID-19 vaccination requirements by receiving available doses of FDA-approved Comirnaty (in Comirnaty-labeled vials), which the Coast Guard has offered to all willing Plaintiffs. *See id.*

Rather than accept that Comirnaty's availability renders their § 1107a and § 360bbb-3 claims unviable, Plaintiffs have made a last-ditch effort to salvage them. Seeking to preempt an eventual finding—following dispositive motion practice—that their statutory claims are moot, Plaintiffs have attempted to concoct a convoluted factual dispute regarding the "legal status" of specific lots of Comirnaty that DoD possesses. Relying on allegations of so-called whistleblowers (which were recounted in a letter from Senator Ron Johnson, *see* ECF No. 25–2), Plaintiffs argued initially that a single lot, "Lot FW1331," is not actually BLA-approved Comirnaty because they doubt it was manufactured at an FDA-approved facility. *See* Pls.' Reply Brief at 7–8 ("PI Reply"), ECF No. 25.

In response to Plaintiffs' unsupported misgivings about Lot FW1331, Defendants submitted the following evidence in the record:

- An official letter dated January 14, 2022, from the Acting Director of FDA's Center for Biologics Evaluation and Research's ("CBER") Division of Manufacturing and Product Quality, approving a facility operated by Pharmacia and Upjohn Company LLC in Kalamazoo,

Michigan ("Pharmacia & Upjohn facility") to manufacture the 30 μg Tris/Sucrose formulation of Comirnaty. The letter was attached to a declaration from Suzann Burk, Director of CBER's Division of Disclosure and Oversight Management, in which she authenticated under penalty of perjury that the letter is an official FDA record.

- An official lot-release letter for Lot FW1331. The letter reflects that Lot FW1331 is a BLA-approved lot of the 30 μg Tris/Sucrose formulation of Comirnaty that was manufactured on January 28, 2022, at the Pharmacia and Upjohn facility, that met all required specifications, and was released by FDA on April 7, 2022. The letter was attached to a declaration from Director Burk, in which she authenticated under penalty perjury that the letter is an official FDA record.

See Decl. of Suzann Burk ("First Burk Decl."), Ex. 1, ECF No. 37-2; Decl. of Suzann Burk ("Second Burk Decl."), Ex. 1, ECF No. 37-1. FDA has subsequently made these official records, and others, available to the public through its Electronic Reading Room. *See* FDA, *Biologics Electronic Reading Room (eFOI)*, https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/biologics-electronic-reading-room-efoi (select the "Pfizer-BioNTech Comirnaty COVID-19 Vaccine Related Records" dropdown menu, and then select the "Frequently Requested Comirnaty Records" tab).[1] Although FDA's public official records establish beyond credible dispute that Lot FW1331 is a BLA-approved lot of Comirnaty, Plaintiffs have now requested that the Court "convene an evidentiary hearing" and permit discovery to determine the "provenance and legal status" of Lot FW1331 and two other lots of Comirnaty that were similarly produced at the Pharmacia and Upjohn facility. *See* Mot. at 1, 3.[2]

[1] The Court may take judicial notice of factual information available on government websites. *See Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322–23 (2007).

[2] Plaintiffs also reference three additional lots: GH9697, GH9702, and GJ6665. *See* Mot. at 2. These three lots were misidentified as Comirnaty in a declaration filed in a related matter. *See* ECF No. 50-3, Decl. of Col. Tonya Rans, *Coker v. Austin*, No. 3:21-cv-01211 (M.D. Fla.). That declaration

ARGUMENT

The Court should deny Plaintiffs' motion to convene an evidentiary hearing and to permit discovery for multiple reasons.

As a threshold matter, the relief that Plaintiffs request is completely inappropriate at this stage of litigation. Plaintiffs ask the Court to conduct "an evidentiary hearing to make findings" that they contend will determine whether their § 1107a and § 360bbb-3 claims are moot and whether the Coast Guard has violated RFRA, the First Amendment's Free Exercise Clause, and the Fifth Amendment's Due Process Clause. *See* Mot. at 1, 21–22; *see also id.* at 21–22 (requesting, in the alternative, that this Court make factual findings in their favor now without conducting an evidentiary hearing). But Defendants have not yet even responded to the Complaint nor filed a dispositive motion to address any of those issues. *See, e.g.*, *Alvarado v. Quarterman*, No. C.A. C-06-371, 2007 WL 38277, at *1 (S.D. Tex. Jan. 4, 2007) (holding that "an evidentiary hearing [wa]s premature" because neither party had filed any dispositive motions).[3] Plaintiffs have offered no reason why this Court should depart from the regular

appended a spreadsheet providing the number of BLA-approved, Comirnaty-labeled vaccines doses and BLA-approved, Spikevax-labeled vaccines doses that DoD possessed on-hand and could make available for administration to service members and other DoD beneficiaries. *See id.* ¶ 4. Due to human error, lots GH9697, GH9702, and GJ6665 were misidentified in this spreadsheet as Comirnaty. *See* Ex. 1, Suppl. Decl. of Col. Tonya Rans ¶¶ 4–5. Each individual immunization site must manually load the logistical information regarding the identification of particular lots, and, in this case, these immunization sites misidentified these three lots. *See id.* ¶ 5. DHA Medical Logistics has contacted the sites to correct the errors and provide the proper vaccine identifications. *See id.* Defendants now provide an updated spreadsheet, with the inaccurate lots numbers removed. *See id.*, Ex. A. Contrary to Plaintiffs' assertions, this human error regarding three discrete vaccines lots has no relevance to the fact that Plaintiffs' statutory claims are moot. *Cf. infra* pp. 6–7.

[3] Nowhere do Plaintiffs suggest that their request for an evidentiary hearing is associated with their motion for a preliminary injunction. Indeed, that is not how they have framed their motion, which asks that the Court make certain factual findings for the purpose of deciding, *inter alia*, the ultimate merits of three of Plaintiffs' claims. *See* Mot. at 1, 21–22. But "it is generally inappropriate for a federal court at the preliminary-injunction stage to give a final judgment on the merits," and "the

course of litigation by attempting to decide the ultimate merits of Plaintiffs' claims at the current stage of proceedings.[4]

I. Plaintiffs' demand for an evidentiary hearing on their § 1107a and § 360bbb-3 claims should be denied.

Plaintiffs' demand for an evidentiary hearing on their § 1107a and § 360bbb-3 claims should be denied for several reasons.

First, Plaintiffs evidently misunderstand why their § 1107a and § 360bbb-3 claims are moot. As Defendants have explained, *see* PI Opp. at 11–12, these statutory claims center on the allegation that DoD and the Coast Guard are mandating that service members take an EUA vaccine to comply with the military's COVID-19 vaccination requirements. But the unvaccinated Plaintiffs are able (and have been for months) to comply with the requirement to become vaccinated against COVID-19 by receiving *any* available doses of Comirnaty or Spikevax (*i.e.*, Moderna's BLA-approved COVID-19 vaccine), including any doses among the nearly 30,000 that DoD possesses, *see* Ex. 1, Suppl. Decl. of Col. Tonya Rans ¶ 6 & Ex. A., as well as any doses that Plaintiffs can obtain in the community. Therefore, contrary to what they seem to suggest, Plaintiffs' § 1107a and § 360bbb-3 claims are moot regardless of whether

findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981); *see also Brown v. Chote*, 411 U.S. 452, 456 (1973) (noting that a district court's issuance of a preliminary injunction "reflected the balance which that court reached in weighing [the preliminary-injunction] factors and was not in any sense intended as a final decision" on the merits, "which would not have been appropriate" under the circumstances). At any rate, Plaintiffs have already had multiple opportunities to present argument and evidence in support of their motion for a preliminary injunction, *see* PI Mot.; *see also* PI Reply, and there is no basis to hold an evidentiary hearing even at the PI stage on the issues Plaintiffs identify in their motion.

[4] Indeed, Plaintiffs consented to Defendants' request to extend the deadline to respond to Plaintiffs' complaint until three weeks after this Court resolves Plaintiffs' motion for a preliminary injunction, ECF No. 32, which this court granted, ECF No. 33. It makes little sense for Plaintiffs to now seek expedited factual findings while that same preliminary injunction motion remains pending.

Lots FW1330, FW 1331, and FW1333 are BLA-approved, because Plaintiffs can take available doses from other BLA-approved, Comirnaty- or Spikevax-labeled lots, including those in DoD's vaccines store whose "legal status" Plaintiffs do not dispute. *See* Mot. at 2. There is thus no need for the Court to determine the "legal status" of the disputed lots in order to find that Plaintiffs' statutory claims are moot. *See, e.g.*, *Smith v. O'Brien*, 59 F.3d 1241, 1995 WL 413052, at *1 (5th Cir. 1995) ("[A]n evidentiary hearing is unnecessary where the district court does not have to resolve complex factual disputes to decide the motion.").[5]

Second, even setting mootness aside, Plaintiffs' request for an evidentiary hearing ignores the fact that their § 1107a and § 360bbb-3 claims are meritless for reasons unrelated to whether a BLA-approved COVID-19 vaccine is currently available. As Defendants explained in their opposition to Plaintiffs' preliminary-injunction motion, *see* PI Opp. at 40 n.35, even assuming the military's COVID-19 vaccination requirements implicates § 1107a, a judge in this District has already held that this statutory provision "only requires that [a service member] have been *informed* that he has a choice whether to get the vaccine or not and to be told of what consequences may follow if he decides to not get the vaccine." *See Miller v. Austin*, No. 4:22-cv-1739 (S.D. Tex. June 1, 2022), ECF No. 9. But no Plaintiff here alleges that he or

[5] Plaintiffs' speculations regarding whether the Coast Guard may someday require them to take an EUA COVID-19 booster, *see* Mot. at 18–19, cannot save their § 1107a and § 360bbb-3 claims. Plaintiffs do not challenge any such requirement in their complaint. *See Arbitraje Casa de Cambio, S.A. de C.V. v. U.S. Postal Serv.*, 297 F. Supp. 2d 165, 170 (D.D.C. 2003) ("[A] complaint may not be amended" through briefing.). Nor do they cite any evidence to support their allegation that the Coast Guard is requiring or may soon require its members to receive a COVID-19 booster. *See* Mot. at 18. Instead, Plaintiffs allege only that the United States Marine Corps is requiring boosters for some of its members under certain circumstances. *See id.* at 18–19. Even if that were true, Plaintiffs serve in the Coast Guard (a DHS component), not the Marine Corps (a DoD component). Therefore, contrary to what Plaintiffs suggest, there is no legitimate basis upon which to find "a reasonable expectation" that the Coast Guard will soon require Plaintiffs to take an EUA COVID-19 booster.

she has not been informed of that choice or the consequences of refusing to vaccinate. Moreover, as explained, *see* PI Opp. at 13, 41, Plaintiffs have no standing and have not identified a private right of action to challenge FDA's compliance with § 360bbb-3. Accordingly, sufficient grounds exist for the Court to reject Plaintiffs' § 1107a and § 360bbb-3 claims without having to conduct a time-consuming evidentiary hearing to address a factual inquiry that is, in all events, immaterial to the resolution of those claims.

Third, assuming *arguendo* that the "legal status" of Lots FW1330, FW1331, and FW1333 is somehow relevant to the Court's ultimate disposition of Plaintiffs' § 1107a and § 360bbb-3 claims, that matter can and should be resolved (if at all) based on official FDA records that conclusively establish that these lots are BLA-approved lots of Comirnaty. As explained above, two of these records are already in the record and are appended to sworn declarations of an FDA official. The first is a letter dated January 14, 2022, reflecting FDA's approval of the Pharmacia & Upjohn facility to manufacture the 30 μg Tris/Sucrose formulation of Comirnaty. *See* ECF No. 37-1, First Burk Decl., Ex. 1. The second is Lot FW1331's lot-release protocol dated April 7, 2022, showing that Lot FW1331 is a BLA-approved lot of the 30 μg Tris/Sucrose formulation of Comirnaty that was manufactured on January 28, 2022, at the Pharmacia & Upjohn facility. *See* ECF No. 37-2, Second Burk Decl., Ex. 1. These documents, as well as the lot-release protocols for Lot FW1330 and Lot FW1333, can be found on CBER's website, which similarly show that both are BLA-approved lots of the 30 μg Tris/Sucrose formulation of Comirnaty that were manufactured, respectively, on January 26, 2022, and February 4, 2022, at the Pharmacia & Upjohn facility. *See* FDA, *Biologics Electronic Reading Room (eFOI)*, https://www.fda.gov/about-fda/center-biologics-evaluation-

and-research-cber/biologics-electronic-reading-room-efoi (select the "Pfizer-BioNTech Comirnaty COVID-19 Vaccine Related Records" dropdown menu, and then select the "Frequently Requested Comirnaty Records" tab).

Plaintiffs' suggestion that this Court should conduct a freewheeling inquiry into the accuracy and validity of FDA's official records and Director Burk's sworn declarations flouts the well-established principle that this type of evidence from a federal agency is entitled to a controlling presumption of regularity and good faith absent clear evidence to the contrary. *See United States v. O'Callaghan*, 500 F. App'x 843, 848 (11th Cir. 2012); *accord United States v. Armstrong*, 517 U.S. 456, 464 (1996); *Maynard v. CIA*, 986 F.2d 547, 560 (1st Cir. 1993) ("An agency's affidavit is accorded a presumption of good faith, which cannot be rebutted by purely speculative claims . . . ." (cleaned up with citation omitted)); *C.G.B. v. Wolf*, 464 F. Supp. 3d 174, 190 (D.D.C. 2020) ("Agency declarations carry a presumption of good faith and are thus entitled to a degree of deference."); *cf. U.S. Postal Serv. v. Gregory*, 534 U.S. 1, 10 (2001) ("[A] presumption of regularity attaches to the actions of Government agencies . . . ."). Indeed, courts routinely reject similar requests to second-guess agency records and declarations based on speculative assertions or insinuations. *See, e.g.*, *FTC v. Bisaro*, 757 F. Supp. 2d 1, 10 (D.D.C. 2010) (finding no basis in the record to disbelieve the agency's declarations and interrogatory answers, which were "entitled to a presumption of regularity and good faith" (citation omitted)); *PlanetSpace Inc. v. United States*, 96 Fed. Cl. 119 (2010) (rejecting plaintiff's "insinuat[ion] that the [agency official] has deliberately mischaracterized" the matters to which he testified because "plaintiff offer[ed] nothing in support of that insinuation save its own conviction," and further noting "the strong presumption of regularity and good faith" to

which the agency official was entitled (cleaned up)); *Powell v. Ky. Fried Chicken*, No. 09-4067, 2010 WL 1687826, at *3 (C.D. Ill. Apr. 26, 2010) (finding "the presumption that officials have properly discharged their official duties" to be "persuasive on the issue of whether the [agency's] records and [the agency official's] affidavit are worthy of belief"); *Savantage Fin. Servs., Inc. v. United States*, 118 Fed. Cl. 487, 491 (2014) (similar); *California v. Trump*, --- F. Supp. 3d ---, 2020 WL 1643858, at *11 (D.D.C. Apr. 2, 2020) (finding plaintiffs' "concerns" insufficient "to rebut the 'presumption of good faith' that the courts typically accord agency declarations and affidavits" (citation omitted)).[6]

Here, Plaintiffs ask that the Court probe the accuracy and validity of FDA's official records and the sworn testimony of its official based on nothing more than rank speculation and misinformed inferences. They have thus fallen far short of presenting clear contradictory evidence or the "well-nigh irrefragable proof" of bad faith or improper motive necessary to overcome the presumption of regularity and good faith that this Court must accord the agency's records and declarations. *See Marine Shale Processors, Inc. v. EPA*, 81 F.3d 1371, 1385 (5th Cir. 1996) (citation omitted); *accord Starr v. EAA*, 598 F.2d 307, 315 (7th Cir. 1978); *Norair Engineering Corp. v. Dist. of Col. Water & Sewer Auth.*, No. 16-cv-1585, 2020 WL 2541935, at *9 (D.D.C. Feb. 26, 2020); *Lee v. Commissioner of Social Sec.*, No. 1:19-cv-953, 2020 WL 6636403, at *5 (W.D.N.Y. Nov. 12, 2020); *see also Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971); *Adair v. England*, 183 F. Supp. 2d 31, 60 (D.D.C. 2002).

[6] *See also, e.g.*, *Charter Tp. of Van Buren v. Adamkus*, 188 F.3d 506, 1999 WL 701924, at *4 (6th Cir. 1999) ("Courts may permit plaintiffs to conduct discovery depositions of agency officials when there are grounds to suspect bad faith or improper behavior not apparent from the administrative record. To overcome the presumption of validity of agency action, however, the plaintiff must show specific facts indicating that the challenged action was reached because of improper motives." (citations omitted)).

Take, for example, Plaintiffs' characterization of FDA's letter approving the manufacturing of the 30 μg Tris/Sucrose formulation of Comirnaty at the Pharmacia & Upjohn facility. Plaintiffs claim that the letter could not have approved the Pharmacia & Upjohn facility to manufacture Comirnaty because the letter does not use "the word 'COMIRNATY'" nor does it require labeling changes to reflect that the Pharmacia & Upjohn facility is a new manufacturing location. *See* Mot. at 13–14. As an initial matter, Plaintiffs cite no statutory or regulatory requirement that FDA refer to a product's trade name in approving a BLA supplement. But more importantly, the approval letter includes a conspicuous reference to Comirnaty's unique BLA number (*i.e.*, 125742) in the upper left-hand corner. *See* First Burk Decl., Ex. 1. That number is listed on FDA's product information page for Comirnaty, *see* FDA, *COMIRNATY*, https://perma.cc/4ADH-7DAQ; can be ascertained from searching FDA's official database of licensed biological products, *see* FDA, *Purple Book: Database of Licensed Biological Products* (last updated Oct. 5, 2022), https://purplebooksearch.fda.gov/advanced-search (enter "125742" in the search bar); and appears in all the approval letters regarding Comirnaty that Plaintiffs append to their motion, *see* ECF Nos. 50-8, 50-13, 50-14, 50-15. And contrary to what Plaintiffs suggest, there was no need for this letter to require changes to Comirnaty's labeling based on the approval of the Pharmacia & Upjohn facility because manufacturing-site information is not a component of the approved labeling for this formulation, *see* FDA, *COMIRNATY*, https://perma.cc/4ADH-7DAQ (follow "Package

Insert – COMIRNATY (gray cap)" hyperlink),[7] nor is it required under FDA's labeling regulations for biologics, *see* 21 C.F.R. §§ 610.60, 610.61.

Plaintiffs infer, moreover, that something must be amiss because FDA's lot-release letters for Lots FW1330, FW1331, and FW1333 reference a submission tracking number (or "STN") that is different than the STN referenced in FDA's letter approving the Pharmacia & Upjohn facility to manufacture the 30 μg Tris/Sucrose formulation of Comirnaty. *See* Mot. at 10 n.6, 14. But Comirnaty's BLA number—125742—appears in the upper left-hand corner of each lot-release letter and FDA's approval letter for the Pharmacia & Upjohn facility. *See* First Burk Decl., Ex. 1; Second Burk Decl., Ex. 2; ECF Nos. 50-5, 50-7. And immediately after the BLA number, the lot-release letters reference STN "36" because that is the submission tracking number associated with FDA's December 16, 2021 approval of the BLA supplement for the 30 μg Tris/Sucrose formulation of Comirnaty, the version of the vaccine that is in Lots FW1330, FW1331, and FW1333. *See* ECF No. 50-8 at 2.[8]

[7] In arguing to the contrary, Plaintiffs misrely on information derived from a National Institutes of Health ("NIH") website, DailyMed, *see* Mot. at 11–13; *see also* ECF Nos. 50-10, 50-11, 50-12, rather than the current approved labeling on FDA's website—the agency with exclusive authority over approval of BLAs and biologics labeling. In fact, DailyMed acknowledges that FDA's website contains the official approved labeling for biologics and includes the following disclaimer: "Differences Between Labeling on DailyMed and FDA-Approved Labeling. The 'in use' labeling on DailyMed may not be identical to the most recent FDA-approved labeling available at Drugs@FDA or the labeling distributed with products. The contents of the 'in use' labeling on DailyMed may not have been verified by FDA." *See* NIH, *About DailyMed*, https://perma.cc/TDB7-VRDC. DailyMed therefore instructs individuals (like Plaintiffs) to visit an FDA webpage "for the most current labeling approved by the FDA for human use in the United States." *Id.* By following that webpage's "Licensed Biological Products with Supporting Documents" link, and then following the link for "Comirnaty," one can access the current approved labeling for the 30 μg Tris/Sucrose formulation, which, as explained above, does not contain any manufacturing-site information. *See* FDA, *COMIRNATY*, https://perma.cc/4ADH-7DAQ.

[8] Regarding Plaintiffs' claim about CDC's COVID-19 Vaccine Lot Number and Expiration Date Report website, CDC has updated the language on the website to clarify that it "contain[s] lot numbers for COVID-19 vaccines made available under either FDA Biologics License Application

Moving on from FDA's records, Plaintiffs take issue with the physical vials in Lot FW1331, noting that they bear no indication that they were manufactured at the Pharmacia & Upjohn facility. *See* Mot. at 14 (citing Senator Johnson's letter pertaining to a shipment from Lot FW1331, but citing nothing relevant to Lots FW1330 or FW1333). But again, FDA regulations do not require that vials of a biologic bear the name of the manufacturing site. *See* 21 C.F.R. § 610.60.

Finally, Plaintiffs suggest that Lots FW1330, FW1331, and FW1333 have already expired in their entirety. *See* Mot. at 15–16. But that argument disregards that the FDA approved a BLA supplement on April 14, 2022, that extended the expiration period for the 30 μg Tris/Sucrose formulation of Comirnaty from 9 months to 12 months, including for lots that had already been manufactured. *See* Ex. 1.[9] And contrary to what Plaintiffs suggest, FDA may permit this FDA-approved BLA supplement to supersede any expiration date that may have been previously stamped on a vial or carton at the time of manufacture.[10] Accordingly,

(BLA) or FDA Emergency Use Authorization (EUA) for distribution in the United States." *See* CDC, COVID-19 Vaccine Lot Number and Expiration Dates, https://perma.cc/9NP4-SHUX.

[9] This document is also on CBER's website. *See* FDA, *Biologics Electronic Reading Room (eFOI)*, https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/biologics-electronic-reading-room-efoi (select the "Pfizer-BioNTech Comirnaty COVID-19 Vaccine Related Records" dropdown menu, and then select the "Frequently Requested Comirnaty Records" tab).

[10] Plaintiffs are incorrect that the approved prescription drug labeling for the 30 μg Tris/Sucrose formulation of Comirnaty contains a lot expiration date. *See* 21 C.F.R. § 201.57 (establishing the requirements for the contents of approved prescription drug labeling, with no requirement to include an expiration date); FDA, *COMIRNATY*, https://perma.cc/4ADH-7DAQ. Moreover, Pfizer keeps recipients informed of any superseding expiration dates by making the approval and updated expiration date readily available by lot number publicly on its website. *See* Pfizer, *Pfizer-BioNTech COVID-19 Vaccine Expiry*, https://lotexpiry.cvdvaccine.com/.

Lots FW1330, FW1331, and FW1333 have yet to expire on account of their approved expiration period.[11]

All told, Plaintiffs' misgivings about Lots FW1330, FW1331, and FW1333 rest on pure conjecture and entirely unsupported inferences that are contradicted by record evidence. That cannot justify this Court setting aside the controlling presumption of regularity and good faith to which FDA's official records are entitled. Therefore, even if the Court were to find that the legal status of these lots had some relevance to the eventual resolution of Plaintiffs' § 1107a and § 360bbb-3 claims, it should nonetheless deny Plaintiffs' request for an evidentiary hearing and discovery regarding matters that are already conclusively established in the record.

II. Plaintiffs' demand for an evidentiary hearing to address the merits of certain claims should also be rejected.

As explained above, *supra* p. 5, it would be highly irregular for this Court to try to hold an evidentiary hearing to resolve the ultimate merits of Plaintiffs' claims at this early stage of litigation, before Defendants have filed a response to the Complaint or a dispositive motion. That is reason alone to deny Plaintiffs' request that the Court convene an evidentiary hearing to determine whether the Coast Guard violated Plaintiffs' rights under RFRA, the Free Exercise Clause, and the Due Process Clause by allegedly using "digital tools" to deny their religious accommodation requests ("RARs") without any "individualized" consideration. *See* Mot. at 1, 21–22.

[11] Plaintiffs make much of the 10-week expiration period for doses that have been refrigerated and thawed. *See* Mot. at 17. But Plaintiffs' evidence does not support their contention that all (or even most) of the doses that DoD possesses from Lots FW1330, FW1331, and FW1333 have been distributed and stored at "refrigerated temperatures." *See id.* (citing ECF No. 50-4 ¶ 10). Moreover, Plaintiffs' allegations regarding a small number of doses at a clinic in Yuma, Arizona, *see id.*, are beside the point. Plaintiffs fail to explain how these allegations are relevant to this case, nor do they contend that they were or will ever be required to take one of those doses.

At any rate, Plaintiffs' various assertions in support of this request are either belied by the record or rest on unsupported inferences. For example, Plaintiffs insist that the Coast Guard has "categorically den[ied] all Coast Guard members' RARs," *see* Mot. at 19, despite the fact that it has granted 12 religious accommodations from the COVID-19 vaccination requirement, *see* Decl. of Brooke Grant, Ex. 1, ECF No. 22-8. Similarly, Plaintiffs suggest that the Coast Guard denied their RARs without "individualized" consideration, *see* Mot. at 1, even though the sworn testimony of Coast Guard leadership, the sworn testimony of Plaintiffs' commanders, and Plaintiffs' RAR packets show that the contrary is true, *see* Decl. of Rear Adm. Eric C. Jones, ECF No. 22-3 ¶¶ 21–37; Decl. of Capt. Jason E. Smith, ECF No. 22-5 ¶¶ 3–8, 10, 19, 25; Decl. of Capt. Hans C. Govertsen, ECF No. 22-6 ¶¶ 3–8; Decl. of Pantelis N. Vasilarakis, ECF No. 22-7 ¶¶ 3–6, 10; Plaintiff Wilder's RAR Packet, ECF No. 22-10; Plaintiff Wadsworth's RAR Packet, ECF No. 22-11; Plaintiff Jorden's RAR Packet, ECF No. 22-12.

Moreover, Plaintiffs draw unfounded inferences from the evidence they submitted regarding the Coast Guard's purported use of "digital tools" in processing RARs and appeals. Plaintiffs point to allegations from some Members of Congress and a putative intervenor claiming that the Coast Guard utilized a Microsoft Access program and a document with template responses to common objections—*i.e.*, the "digital tools"—in helping to draft decision letters for some service members' RARs or appeals. *See* ECF Nos. 43-1, 52-1. But even assuming those allegations are true, that would in no way support the inference that the Coast Guard "automatically" denied Plaintiffs' RARs and appeals without considering their

individual circumstances. *See* Mot. at 1, 19–21.[12] And that inference is all the more unjustified when considered in light of the evidence and sworn testimony already in the record, which demonstrates that the Coast Guard conducted an individualized evaluation of the RARs and appeals of each unvaccinated Plaintiff currently serving in the Coast Guard. *See supra* p. 14; PI Opp. at § I.B. Plaintiffs present no basis on which to allow discovery to hold evidentiary proceedings at this stage on these issues.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' motion for an evidentiary hearing.

Dated: November 28, 2022

Respectfully submitted,

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[12] Plaintiffs maintain that such an inference would be consistent with (i) a recent report by DoD's Acting Inspector General ("IG"), which contained "DoD-wide preliminary findings"; and (ii) a so-called whistleblower's allegations regarding the Navy's use of "digital tools" in processing RARs. *See* Mot. at 20–1. But Plaintiffs apparently do not understand that the Coast Guard is a component of DHS, not DoD. The Coast Guard thus falls outside the purview DoD's IG report. Nor do Plaintiffs' allegations regarding the Navy have any relevance to this case, because contrary to what Plaintiffs seem to think, *see* Mot. at 20, the Coast Guard has not been a part of the Department of the Navy since World War II, *see* Congressional Research Serv., *Defense Primer: Department of Navy* (updated Oct. 25, 2021), https://crsreports.congress.gov/product/pdf/IF/IF10484/20.

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CERTIFICATE OF SERVICE

I hereby certify that on November 28, 2022, I electronically filed the foregoing document with the Clerk of Court using this Court's CM/ECF system, which will notify all counsel of record of such filing.

/s/ Cassandra Snyder
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